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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,586	12/21/2004	Kazushige Moriyama	263494US0PCT	7701
22850	7590	01/03/2006		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER DIRAMIO, JACQUELINE A	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/518,586		MORIYAMA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Jacqueline DiRamio		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/21/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 10 – 12 in the reply filed on October 31, 2005 is acknowledged. The traversal is on the ground(s) that a lack of unity does not exist between Groups I – III because they relate to a product, method of making, and method of using the product. This is not found persuasive because the product recited in Group I lacks novelty because it is anticipated by Bronstein et al. (US 5,112,960), as set forth on the record in the previous office action. Therefore, because the product is known in the art, Groups I – III lack unity and can be broken into separate and independent inventions.

The requirement is still deemed proper and is therefore made FINAL.

Applicant has requested that when the claims of Group II are found to be allowable that Groups I and III be rejoined. The elected invention of Group II is drawn to a method (process). As claims drawn to a product have not been elected for prosecution, the non-elected claims are not subject to rejoinder (see MPEP 821.04 and 2113).

### ***Claim Objections***

Claims 10 – 12 are objected to because of the following informalities:

Claims 10 – 12 recite dependencies to the claims of the non-elected invention of Group I, which is incorrect.

Additionally, the claims are all found to have incorrect multiple dependencies and therefore, the examination of the method found in claims 10 – 12 will be drawn to the chemiluminescence enhancer recited in claim 1 only.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 – 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Akhavan-Tafti et al. (US 6,045,727).

Akhavan-Tafti et al. teach a chemiluminescence method of reacting phosphatase-labeled specific binding partners in the presence of a chemiluminescence compound with an added chemiluminescence enhancer, wherein the method can comprise a solid phase immunoassay using an antigen and/or antibody immobilized onto fine solid carriers dispersible in a liquid medium. The chemiluminescence enhancer typically comprises a surfactant compound, such as a quaternary ammonium or phosphonium salt (see column 14, lines 49-67; column 15, lines 1-36; column 22, lines 37-67; column 23, lines 1-27; column 24, lines 39-67; and column 25, lines 1-53).

With respect to Applicant's claims 11 and 12, the immunoassay can utilize particles in the presence of the chemiluminescence enhancer, wherein the particles are specifically magnetic particles (see column 25, lines 1-53; particularly lines 5 and 52).

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Voyta et al. (GB 2 233 451 A).

Voyta et al. teach a chemiluminescence method of reacting alkaline phosphatase as an enzyme of a labeled body in the presence of a chemiluminescence compound with an added chemiluminescence enhancer, wherein the method is utilized with a solid phase immunoassay using an antibody immobilized on fine solid carriers dispersible in a liquid medium. The chemiluminescence enhancer typically comprises a water soluble polymeric quaternary ammonium salt (see p4, lines 5-27; p22, lines 27-29; and Example 46 on pages 29-30).

With respect to Applicant's claim 11, the immunoassay can utilize beads (particles) in the presence of the chemiluminescence enhancer (see p29, lines 8-11).

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bronstein et al. (US 5,753,436 or US 5,112,960).

Bronstein et al. teach a chemiluminescence method of reacting alkaline phosphatase as an enzyme of a labeled body in the presence of a chemiluminescence compound with an added chemiluminescence enhancer, wherein the method is utilized with a solid phase immunoassay using an antigen and/or antibody immobilized on fine

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solid carriers dispersible in a liquid medium. The chemiluminescence enhancer typically comprises a water soluble polymeric quaternary ammonium, phosphonium or sulfonium salt (For '436 patent, see column 7, lines 44-45; column 8, lines 49-67; column 9, lines 1-10; column 10, lines 1-13 and column 15, Example 2; For '960 patent, see column 5, lines 21-29; column 11, lines 1-32; columns 19-20, "Solid State Assays; and column 29, Example XII).

With respect to Applicant's claim 11, the immunoassay can utilize beads (particles) in the presence of the chemiluminescence enhancer (For '436 patent, see 15, Example 2; For '960 patent, see column 29, Example XII).

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,094,939).

Okada et al. teach a chemiluminescence method of reacting alkaline phosphatase as an enzyme of a labeled body in the presence of a chemiluminescence compound with an added chemiluminescence enhancer, wherein the method is utilized with a solid phase immunoassay using an antigen and/or antibody immobilized on fine solid carriers dispersible in a liquid medium. The chemiluminescence enhancer typically comprises a polymeric quaternary ammonium salt (see column 5, lines 37-68; column 6, lines 1-62; column 8, lines 1-30; and claim 11).

With respect to Applicant's claim 11, the immunoassay can utilize beads (particles) in the presence of the chemiluminescence enhancer (see column 6, Examples 1 and 2; and column 8, Examples 5 and 7).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voyta et al., Bronstein et al., or Okada et al. in view of Ho (US 2002/0164271).

The Voyta et al., Bronstein et al. and Okada et al. references fail to teach the particles utilized with the immunoassay comprise magnetic particles.

Ho teaches bioassays utilizing microspheres, wherein the microspheres can comprise magnetic beads (particles). The magnetic beads are ideal for solid phase assays and can be utilized with radioimmunoassay, ELISA or chemiluminescence immunoassays. The magnetic particles are used to efficiently concentrate analyte molecules, by easily separating the particles from the liquid phase with a small magnet (see paragraph [0004]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the method of Voyta et al, Bronstein et al. or Okada et al. the use of magnetic particles as taught by Ho because Ho teaches that magnetic particles are ideal for solid phase immunoassays and the magnetic particles are beneficial in order to efficiently concentrate analyte molecules.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1641



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